Exhibit 19

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Corporate Headquarters 3945 Lakefield Court Suwanee, GA 30024 (770) 866-3200 FAX (770) 866-3259



3nd Supplemental MDL Report

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Analysis of Non-Historical J&J's Talcum Powder Consumer Product Containers and J&J Chinese Historical Talc Retain Samples



William E. Longo, Ph.D., CEO

Materials Analytical Services, LLC 3945 Lakefield Court Suwanee, GA 30024

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3rd MDL Supplemental Report

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This supplemental report contains the following new information obtained by MAS since the 2nd Supplement MDL Report was issued on February 1, 2018. MAS has analyzed 44 J&J talcum powder products for both chrysotile and amphibole asbestos. These additional samples focus primarily on Chinese sourced talcum powder that J&J used from 2004 to 2022 in North America, and three additional Vermont sourced JBP samples.

Also, when the last MDL report was issued, MAS was not analyzing cosmetic talc samples for chrysotile using the heavy liquid separation (HLS) sample preparation method. After reviewing the Colorado School of Mines (CSM) protocol for the analysis of chrysotile using a HLS sample preparation method with PLM analysis, MAS worked on developing a more efficient protocol for the detection of chrysotile in cosmetic talc samples. The Colorado School of Mines developed this method.

MAS has analyzed 40 JBP containers that were all manufactured with J&J's Chinese talc source. MAS has also analyzed 11 J&J Chinese talc retains along with two additional JBP Vermont sourced talc containers.

All additional J&J talcum powder product analysis Reports have been previously provided to defense counsel on behalf of J&J, and I have been questioned by J&J defense counsel on all of these sample analysis reports during numerous depositions. These reports provide all of the sample chain-of custodies, the analytical protocols used for that particular set of samples and results.

Therefore, this Supplemental report will only contain the results for the 43 additional analysis that was performed after our last MDL Supplement Report was issued on February 1, 2019.

J&J Vermont Talc Source

Table 1 provides the J&J sample information and analytical results for the three JBP containers were talcum powder was sourced from Vermont.

J&J Chinese Talc Source

The overall results show that out of the 43 J&J talcum powder samples analyzed, that contained Chinese sourced talc, 40 or 93% were positive for either amphibole asbestos and or chrysotile. As discussed above, the Reports for 41 of the 43 JBP and STS sample sets have been provided to J&J, and in those reports will contained the full methodology used for each set of sample analysis. Therefore, there was not any reason to duplicate the methodology here in this report.

Besides J&J talcum powder container samples, MAS also received 11 Chinese retained talc samples that consisted of two Imerys retains and nine J&J retains. The results of these 11 samples are shown in Table 7. Tables 1 thru 7 can be found at the end of this report.

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All 11 of the Guangxi providence talc sourced sample retains were found to be positive for chrysotile asbestos at a concentration that ranged from 0.0008% to 0.002%. For the 42 Chinese sourced J&J talcum powder products and 11 retain samples, gave a total of 50 samples were positive for asbestos out of the 53 samples (94%).

DISCUSSION/CONCLUSION

Colorado School of Mines (w HLS) Sample Preparation of Cosmetic Talc

This section reviews the development of the double density cosmetic talc sample preparation method, by the Colorado School of Mines Institute, on behalf of J&J, for the concentration of chrysotile and amphibole asbestos in talc samples.

The sample preparation part of the MAS chrysotile analysis is based on the work done by the CSMP in the early 1970's for the detection specifically for possible chrysotile and amphibole asbestos in J&J sourced Vermont talcum powder, from the Frostbite mine using, double heavy liquid separation (<2.9 g/cc & >2.9 g/cc).

An overview of this method development by CSM is as follows:

In a January 17, 1973 Windsor Minerals document sent by R.N. Miller to Mr. Bill Ashton of J&J, subject: "Core samples, diamond drill holes, Frostbite mine" informing Bill Ashton that Windsor Minerals was sending 1/8 split of our retain samples from the cosmetic ore sampling done in these holes. The memo goes on to say, "This is the material which was sent to Colorado identified as CN core which we conducted our pilot production runs which yielded Grade 66 material. (JNJ000682638)¹

Cosmetic Talc Core Samples mailed to Colorado School of Mines:

Hole Numbers

- 1. 30-71-S 4. 32-71-S
- 2. 30-B-71-S 5. 34-71-S
- 3. 30-C-71-S

¹ January 17, 1973 Windsor Minerals document sent by R.N. Miller to Mr. Bill Ashton of J&J, subject: "Core samples, diamond drill holes, Frostbite mine".

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February 26, 1973 Colorado School of Mines (CSM) document for, Project no. <u>C10704</u>, reported their analysis to W.H. Ashton, where these same five Frostbite core samples were prepared with heavy liquid separation (HLS) with two different densities (<2.9 & >2.9) and with acid leaching. (JNJNL61_00008084 thru JNJNL61_00008089). The "as received samples" and were first analyzed using x-ray diffraction and microscopic studies without HLS.

The results stated that "Relative to possible asbestos type minerals, samples 30-71-S and 30-B-71-S contained slight traces of tremolite-actinolite minerals. Sample 32-71-S is suspected to contain a very minor amount of serpentine which maybe chrysotile".

As further outlined in the 2/26/1973 Report, the next phase of study was that the 5 Frostbite talc ore samples were first fractionated using heavy liquid separation (HLS) and then with acid dissolution, then analyzed by XRD. The report describes the HLS method as follows: Each of the ground talc ore was separated into fractions by centrifugation in heavy liquids: specific gravity <2.90 and specific gravity >2.90. After the x-ray diffraction of the >2.90 specific gravity fractions, the sample was leached with 1:1 HCL to remove magnesite. The insoluble residue was then examined for amphiboles with a petrographic microscope. In both Phase 1 and Phase 2, possible serpentine was detected in Frostbite ground talc ore sample 32-71-S.

The last phase of this analysis, CSM attempted to verify the presence of serpentine in sample

32-71-S < 2.65 fraction by step scan x-ray diffraction over the critical diffraction peaks of serpentine which is in the 7Å and 14Å region, "the initial result suggested that serpentine, not chlorite, was present."

Microscopic examination of the <2.65 fraction identified a "very minor (1%) amounts of possible serpentine fibers" that was facilitated by staining with 1% iodine in glycerin.

The report recommended that further work be done on this sample (32-71-S). It has been suggested in the past by some that this statement meant that more work was needed on the heavy liquid separation sample preparation method. That suggestion is not true.

April 2, 1973 Colorado School of Mines (CSM) document for Project no. <u>C10704</u>, reported their analysis to W.H. Ashton, where the primary objective of the studies was to determine the presence or absence of tremolite and chrysotile in talc bearing head samples labeled 1 through 4.

For the HLS sample preparation and analysis, by CSM, the four head talc ore samples were first ground into two size ranges of minus 200 plus 325 and minus 325. The samples were then prepared with CSM's double heavy liquid separation method and acid dissolution, analyzed by XRD and or optical microscopy. For optical microscopy of tremolite analysis, RI fluid 1.600 was used for their PLM analysis of the tremolite asbestos. MAS has been criticized in the past for

using 1.605 RI fluid because it was not high enough as suggested by J&J's experts, even though the CSM used 1.600 RI fluid which is a lower RI fluid.

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Colorado School of Mines Results:

Chrysotile (HLS < 2.65 g/cc)

- 1) Minus 200 plus 325 mesh: Chrysotile abundance was estimated as <0.0001% in sample 3 and <0.0006% for sample 4.
- 2) Plus 325 mesh: Chrysotile abundance was estimated as <0.0007% in samples 2, 3 and <0.0006% for sample 4.

Tremolite (HLS >2.90 g/cc)

- 1) Minus 200 plus 325 mesh: possible tremolite was found in sample 2 is estimated at <0.002%
- 2) Minus 325 mesh: No tremolite was detected in any of the four samples.

These four samples were labeled "head" samples which defined as average grade feed that goes into the mill before the flotation process. There was no identification of the source of the talc samples in the April 2, 1973 Colorado School of Mines Report. However, it is most likely these head samples were collected in the same area that sample 32-71-S was collected from the Frostbite mine in which the very last sentence states. The reason for this is that in the Colorado School of Mines 2/26/1973 report to Dr. Ashton, "that further work be done on this sample 32-71-S".

It would seem reasonable to conclude that the next set of talc samples analyzed was fulfilling that further work statement about Frostbit sample 32-71-S. Also, there were only 36 days between the CSM February and April reports, and all three of these reports have the same CSM Project no. C10704.

December 27, 1973: Colorado School of Mines Research Institute prepared the following report for Johnson & Johnson, "A Procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers for Project C10704". (JNJ 000268037 to 045).²

This CSM report provides the methodology using double density heavy liquid separation for chrysotile and amphibole asbestos. It reports a detection limit of 10 ppm (0.00001%) and verification of asbestos types, after separation, was done by optical microscopy.

This method also stated the following: "Electron Microscopy examination employing selected area electron diffraction and/or x-ray emission spectrography may be required in order to

² December 27, 1973, Colorado School of Mines protocol entitled "A procedure to Examine Talc for the Presence of Chrysotile and Tremolite-Actinolite Fibers" Herman Ponder Director, Jerry Krause Senior Scientist and James Link Director Mining Division.

specifically identify small fibrous particulates". The Colorado School of Mines recognized that TEM would be needed to identify for small particles.

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Nowhere in this report was there even a suggestion by the Colorado School of Mines that their double density heavy liquid method, for sample preparation, for both chrysotile and amphibole asbestos, was anything but a sound scientific method.

In fact, this sample preparation was approved and signed off by the following individuals from the Colorado School of Mines Research Institute: Herman Ponder, Director, James M. Link, Director Mining Division, and Jerry Krause, Senior Scientist Mining Division.

In the Introduction Section, the second paragraph states the following:

"the impurity level becomes very low (<<1%), it is necessary to examine increasing amounts of sample in order to detect the impurity. As a result of the requirement to detect the proverbial "needle in a haystack," we have evolved a procedure which preconcentrates the impurities prior to examination. The net effect is that a large initial sample is fractioned in order to reject the majority from further examination."

This was one of the reasons that MAS decided to use heavy liquid separation in late 2016 for cosmetic talc analysis as described above by the Colorado School of Mines.

Johns-Manville

Another indication of how confident the Colorado School of Mines was in their double density separation method is that they informed Johns-Manville that they thought this heavy liquid separation method they developed, was good enough to be considered for a patent (JNJMX68 000007044 to 000007046).

In an October 29, 1973 letter from V.E Wolkodoff of Johns-Manville to Mr. Caneer, Colorado School of Mines, in response to a phone call from Mr. Caneer, Mr. Wolkodoff writes the following:

"Specifically, we were interested in your advanced technology used to separate felted masses of asbestos by heavy liquid separation preparatory to staining of chrysotile by iodine as worked out by Morton and Baker of Johns-Manville".

Mr. Wolkodoff further writes, "I understand your position completely on specific techniques being worked for other companies which are proprietary and, as you had indicated, will probably be patented."

This letter confirms CSM was both developing this sample preparation method for J&J, and thought it was such an advancement in talc sample preparation technology for PLM analysis, they were considering to protect it with a patent.³

With that said, I have seen no indication or documents that J&J's CSM double density talcum powder sample preparation method was ever patented, or shared with the FDA when they struggled with their own development of a concentration method, or over a period of 50 to 60 years, there is no evidence that J&J ever had their main outside QA labs (McCrone or the R.J. Lee Group) use the much superior CSM sample preparation method, when they were analyzing J&J's talcum powder by XRD, PLM and or TEM for asbestos. The lack of use of the CSM sample preparation method by these two outside labs, explains why hundreds, if not thousands of J&J's talc sample analysis for asbestos analysis were found to be non-detects by the McCrone and RJ Lee labs.

I believe the reason that the CSM talc sample concentration preparation method for chrysotile and amphibole asbestos, was never adopted by the talc and cosmetic industries, can be summed up by the following statements by Dr. Robert Rolle of J&J in two documents. The first document is a May 22, 1973 Report entitled "Proposed Specs for Analyzing Talc for Asbestos". On the third page concerning Dr. Pooley's preconcentration method for tremolite, Dr. Rolle states, "This technique has not been written up yet, but evidently when applied to Vermont talc, 0.5% of the tremolite-type is found." Dr. Nashed of J&J received this report on May 23, 1973 (JNJAZ56_000001892 to 1989)⁴

"The limitation of this method is that it may be too sensitive."

The second document is a February 18th, 1975 memo to Dr. Rolle where he states, "I have also enclosed our test method for the proposed Xray technique which was drawn up by Boots Ltd in conjunction with Dr. Pooley" (JNJNL61_000062953)⁵

"We deliberately have not included a concentration technique as we felt it would not be in worldwide company interest to do this."

Other Asbestos Concentration Methods for Cosmetic Talc Yardley LTD. Method

A J&J produced document (JNJ00026450 to 4509 **redacted**) that also has a Bate stamp number DX8011.0010 to .0010 **un-redacted**) entitled <u>"A Method for the Separation of Impurities from Talc"</u>, is a double density separation sample preparation method that is very similar to the CSM

³ October 29, 1973 letter from V.E Wolkodoff of Johns-Manville to Mr. Caneer, Colorado School of Mines.

⁴ May 22, 1973 Report where the Subject, entitled "Proposed Specs for Analyzing Talc For Asbestos".

⁵ February 18th, 1975 memo to Dr. Rolle.

double density sample preparation method.⁶ The primary differences involves the density for the heavy liquid that was used. Where the CSM method uses 2.65 g/cc for the chrysotile and >2.90 g/cc for the amphibole asbestos, the Yardley method uses 2.69 g/cc for chrysotile and 2.83 g/cc for amphibole asbestos. Also, the Yardley method uses a centrifuge speed of 3,000 rpm for 5 minutes, the CSM method uses a centrifuge speed of 800 rpm for two intervals of 30 minutes. The 1991 published Blount HLS sample preparation method for amphibole asbestos, uses 2.81 g/cc and a centrifuge speed of 7,000 rpm for 10 minutes.

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Each of these heavy liquid separation methods are using slightly different HL density liquids and different centrifuge speeds and times. The main point of this is that scientists are apparently using different HL densities and centrifugation times in an effort to increase analytical sensitivity. There is no right or wrong, the only thing important is that heavy liquid separation of asbestos from talcum powder is a well-researched method developed by J&J almost 50 years ago, published by Dr. Blount in 1990/91, and is also an International Standards Organization protocol (ISO 22262-1 &2) method, as well as used by the New York Environmental Laboratory Accreditation Program.

Physical Prosperities of Tremolite & Anthophyllite

In the December 27, 1973 Colorado School of Mines Research report, it is noteworthy that tremolite was detected in the minus 200 plus 325 samples, but not in the minus 325. These findings are consistent with the Pang et al. publication in 1987.7 For this study, they spiked talc with tremolite (1.0% and 0.1%) and ground these samples for two size ranges: 1) 50% was minus 325 and 2) 100% minus 325.

The results showed that for the TEM analysis (100 grid openings) the 1% spiked tremolite sample, at 50% minus 325, the number of tremolite fibers detected was 1,592, and for the 100% minus 325, the number of tremolite fibers was reduced to 91 structures or 5% detected.

For the 0.1 wt. percent, for the TEM analysis (100 grid openings) the 0.1 % tremolite spiked sample at 50% minus 325, the number of tremolite fibers detected was 88 and for the 100% minus 325, the number of tremolite fibers was reduced to 0 structures detected.

What is important about this study, is first that the tremolite used was characterized by the authors as tremolite asbestos/asbestiform due to the aspect ratio. Second, the asbestos fibers/talc spiked samples were ground so that there were two different particle size populations for two sample sets, 1st set, 50% of the sample would pass through a 325 mesh per inch sieve (45 µm opening), 2nd set, 100% of the sample would pass through the 325 mesh.

⁶ A Method for the Separation of Impurities from Talc

⁷ Thomas W.S. Pang, et al., "Determination of tremolite Asbestos in Talc Powder Samples" Ann. Occup. Hyg., Vol. 31, No. 2, pp 219-225, 1987.

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The Pang publication showed that when the talc was ground to the point that the size of the talc particles was small enough that 100% of the powder went through a 325 mesh, it either greatly reduced (1.0% spiked sample) or eliminated (0.1%), which is consistent with what Colorado School of Mines reported to J&J in their April 2, 1973 Protocol.

The reason for the tremolite asbestos being ground up is due the physical properties of tremolite asbestos, as well as anthophyllite asbestos, where both tremolite and anthophyllite have both low tensile strengths causing (brittle), and not flexible like chrysotile, and to a lesser degree, amosite and crocidolite.⁸ Since tremolite asbestos is brittle, the grinding to a minus 325 mesh size, by both the CSM and the Pang research, simply broke the tremolite fibers/bundles into particles.

The CSM results also showed that chrysotile was not affected when ground to a minus 325 mesh size because chrysotile has high tensile strength, good flexibility and is the reason that most all asbestos-containing cloth is woven out of chrysotile and not ever from tremolite or anthophyllite asbestos. However, the size and width of the chrysotile bundles may be affected in the milling operation and that would account for the 5 to 20 μm in length to 2 to 4 μm in width range that we see in the cosmetic talcs, as well as the UCC SG-210 chrysotile.

Additionally, this data suggests that that cosmetic talc being milled to either a minus 200, and in some cases, a minus 325, is lowering the tremolite and or anthophyllite concentrations in the talcum powder, unless the concentration is so high in the talc ore, that a significant amount of the amphibole asbestos survives the milling process as demonstrated with the MDL samples in our 2-1-2019 report as well as for the samples reported here that were positive for either tremolite or anthophyllite.

The Pang study clearly shows that milling talc to either minus 200 or minus 325 sieve size greatly reduces the amount fibrous tremolite asbestos detected by TEM, which would also have an effect on the amount detected by PLM.

For many years the Cosmetic, Toiletry Fragrance Association (CTFA) J4-1 method for the detection of asbestiform amphibole minerals (tremolite or anthophyllite) in cosmetic talc first analyzed by XRD and if the talcum powder sample is negative for either tremolite and or anthophyllite, the analysis is stopped and the sample declared as not to not contain asbestos. On the other hand, if the sample is positive by XRD then the sample is analyzed by PLM to determine if the tremolite or anthophyllite is positive.

The J4-1 sample preparation method for PLM is located on page 10 at Note 1, and states the following: Talcs to be analyzed and the tremolite used to prepare standard samples must be

⁸ M.A. Vos, Asbestos in Ontario, Industrial Mineral Report, Ontario Department of Mines and Northern Affairs, Ontario, Canada 1971.

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finer than 325 mesh (maximum particle size of 44 microns). The Tekmar Analytical Mill (Model A-10) is recommended.

Since the J4-1 PLM method requires that 100% talc sample be milled to a minus 325 sieve size, will cause most, if not all of the fibrous tremolite asbestos to be ground to non-asbestos particulates if tremolite asbestos is present in the sample, causing many false negative results to be reported.

This discussion goes to the whole issue of the general geological definition of "asbestiform" that appears in many of the standard TEM protocols, including the ASTM D5755-09 dust method that I was the primary author. ⁹ This general definition is as follows:

"asbestiform-a special type of fibrous habit in which the fibers are separable into thinner fibers and ultimately into fibrils. This habit accounts for greater flexibility and higher tensile strength than other habits of the same mineral."

This is only a general definition that a geologist might be interested in when evaluating a potential asbestos mine, since the more fibrous the asbestos deposit, the more economical value the mine would have. The economic value which depends on the grading of the asbestos where the most important factors are fiber or fiber length, tensile strength, flexibility, and spinnability among others, as shown in the Table 8.

Table 8
Physical Properties of Asbestos

Asbestos Type	Tensile strength (PSI)	Flexibility	Spinnability
Chrysotile	80,000-100,000	High	Very Good
Amosite	16,000 - 90,000	Good	Good
Crocidolite	100,000-300,000	Good	Good
Tremolite solid		Poor	Poor
solution series	<1,000 - 8,000		

Poor

M.A. Vos, Asbestos in Ontario

As the above table shows, the physical properties of tremolite, and anthophyllite asbestos have low tensile strength, both poor flexibility and spinnability, as compared to the other three asbestos types found in asbestos added products, and yet are regulated asbestos.

In a recent publication by Germine & Puffer entitled "Anthophyllite Asbestos from Staten Island, New York: Longitudinal Fiber Splitting", the authors concluded that the low quality

4,000 or less

Anthophyllite

Poor

⁹ ASTM D5755-09 Dust Method

characteristics of anthophyllite asbestos from the Staten Island mine, are consistent with the anthophyllite asbestos of the Finland mine. 10 These characteristics include low aspect ratios, longitudinal splitting rather than crystal growth and "rather brittle such that they could not be woven in the manner of high quality chrysotile." This paper verifies that that anthophyllite asbestos is brittle causing low tensile strength, not flexible or separated into single fibrils, and would not meet the disputed general geological asbestiform definition for commercial asbestos added products, but they also state in the last sentence of their paper "anthophyllite and amosite fibers are not asbestiform like chrysotile fibers but are never less potentially dangerous."

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If this asbestiform definition was meant to be more than a general geological one, then the various analytical methods, using this definition, would have incorporated into the analytical methods, how to measure the tensile strength or flexibility of the microscopic asbestos fibers and bundles. Of course, the methods do not provide a means to measure flexibility and tensile strength since that type of measurement is impossible to accomplish by either PLM or TEM. Also, none of these analytical methods define what high tensile strength is, or how many measurements constitute a population.

MAS's PLM Analysis of Chrysotile in Cosmetic Talc using the CSM Method

The PLM analysis performed by MAS showed that the six containers that were analyzed by the CSMP sample preparation method with HLS was positive for chrysotile asbestos.

MAS's PLM analysis was able to both detect and determine the amount of chrysotile bundles in the sample with HLS because MAS uses PLM microscopes that has higher resolution and analytical sensitivity capabilities, than your standard PLM microscope which is more suited for analyzing asbestos added products (AAP).

In AAP (chrysotile) samples as compared to cosmetic talc samples, has a much higher population of very large size chrysotile bundles and orders of magnitude higher concentration levels of chrysotile in these types of products.

The PLM analysis of AAP samples does not challenge the resolution of the typical PLM microscope optics, or burden the microscopist with very long sample analysis times. For example, in most PLM labs, including MAS's, the typical time required for an experienced PLM microscopist to analyze asbestos added products (AAP), where the majority of the AAP samples

¹⁰ Mark Germine and John H. Puffer, "Anthophyllite asbestos from Staten Island, New York: Longitudinal fiber Splitting", Archives of Environmental & Occupational Health, (2021) https://doi.org/10.1080/19338244.2021.1873095

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contain approximately 10 to 25 % asbestos, will only take about 15 and 20 minutes to complete the analysis.

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With a cosmetic talc sample on the other hand, a typical PLM analysis at MAS, for either chrysotile or amphiboles asbestos, would routinely take 2 to 4 hours for a positive sample and a minimum of 20 minutes to hour for a negative sample, if there are no pigments in the sample. In order to both detect and analyze the small size of the chrysotile bundles (10 to 20 μm in length), that are typically found in cosmetic grade talcum powder, through the use of dispersion staining, the PLM microscope must have "flat" objective lenses, and a HD video camera attached to the PLM microscope that is interfaced to a high definition monitor.

The MAS PLM microscopes are Leica DM2700P PLM microscopes, where all of the objective lens, including the 10X central stop dispersion lens are the flat type, also known as infinity lens, LED light source, and are coupled with state-of-the-art HD digital camera and 37" HD monitor. To detect these size chrysotile bundles, it is highly recommended that this type of PLM microscope setup should be used for the PLM analysis of cosmetic talc samples.

It is also my opinion that the PLM analyst must first analyze prepared talcum powder standards, containing UCC SG-210 or RG-144 chrysotile, to become familiar with both the size of chrysotile structures found in cosmetic talc, as well as the difference in the refractive indices for the chrysotile as compared chrysotile added products.

Both the RG-144 and RG-210 Calidria chrysotile and the chrysotile found in the talcum powder samples typically shows central stop dispersion colors (CSDS) from blues (α) to golden yellows (γ) in 1.550 liquid, and blue to a dark gold in 1.560 liquid. MAS has been reporting this range of CSDS colors for the chrysotile detected in the cosmetic talc samples for almost two years using 1.550 RI liquid. During that time, defendant experts, retained by a number of cosmetic talc manufacturers, and have repeatedly testified that MAS's CSDS findings are not appropriate for chrysotile. Therefore, in their opinions, MAS was and has been misidentifying fibrous/platy talc edge or cellulose as chrysotile.

Additionally, Dr. Gunter, while working as a defense expert for Gold Bond defense counsel, analyzed samples of RG-144 and SG-210 Calidria chrysotile, that MAS provided to him, and he confirmed in a recent deposition that "Calidria chrysotile can produce a range of CDSC colors from bluish to golden-yellow in 1.550 liquid. 11 Dr. Gunter's Calidria chrysotile results are consistent with our laboratory's findings, which validates our PLM chrysotile findings in the cosmetic talc samples. 12

¹² Deposition of Dr. Mickey Gunter, Woods, Jesse & Sarah vs. Kolmar Laboratories Inc. et al. Supreme Court in the State of New York, County of Monroe, #E202000384

¹² Expert Report, October 9, 2023 "Comparison of Ri's and Chrysotile Structure Size Union Carbide's SG-210 Chrysotile product from the Coaling Mine California, Montanan Talc, Fibrous talc and Reduced Size NIST 1866b Chrysotile Standard.

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Dr. Gunter's testimony about his Calidria CSDS results is in direct contradiction to his original criticism of the "yellow-gold" dispersion color, as well as Dr. Sanchez and Mr. Seagrave's past testimony on this issue.

It is my opinion, that when these defense experts were testifying that our laboratory was misidentifying fibrous talc or talc plates on edge for chrysotile based on the CSDS "yellow color", as it turns out, the opposite was true, they were the ones misidentifying chrysotile as fibrous talc or talc plates on edge.

Birefringence Measurements

The key optical property to differentiate fibrous talc from chrysotile asbestos, when using the PLM method, is determining the difference in the birefringence (BIR) value between these two elongated minerals. Most PLM analysts will just use the PLM cross-polar condition to visually estimate the magnitude of the BIR (Low, Moderate or High) by the amount of brightness and change in wavelength colors that are observed.

This visual estimate of the amount of birefringence is typically done under cross-polar conditions and is a subjective interpretation by the PLM analyst, therefore, can lead to errors. A more accurate determination of BIR is to calculate the numerical BIR value by simply subtracting the measured perpendicular RI from the measured parallel RI (n \parallel - n $_ \parallel$ _).

The subtracted BIR results give the analyst a numerical birefringence (BIR) value that is either classified as Low (<0.01), Moderate (0.01 to 0.05) and High (>0.05).

Fibrous talc and/or talc plates on edge will have a calculated BIR value that is typically at the high end of Moderate (0.045) to greater than 0.05 which is in the High BIR range. Chrysotile on the other hand, will have BIR values that range from the middle to the upper end of the Low range to the lower end of the Moderate range. The average calculated range BIR's, for the detected chrysotile bundles from the powder samples for CSM PLM method had a range of 0.005 to 0.017 which falls in the LOW end of BIR to the low end of Moderate classifications when done by calculation.

The BIR difference between fibrous talc and chrysotile, as demonstrated by MAS, is also verified by the EPA in their 600/R-93/116 PLM methodology document as shown in Table 2-2, page 21.

Table 2-2, "Optical Properties of Asbestos Fibers", provides four sets of refractive indexes measured from chrysotile bundles that have an overall average BIR of 0.011. In that same table, EPA published a range chrysotile BIR's of 0.004 to 0.017 (Low to moderate). This BIR range reported by EPA, was from the Maximum and Minimum values obtained from references 2, 11, 12, and 18 located in Section 2.2.

The method that EPA used for the BIR was to subtract the highest alpha from the highest gamma, then subtract the lowest alpha from the lowest gamma. The EPA referenced BIR PageID: 193708

method, is the same way that MAS determined the BIR for the chrysotile bundles found in the J&J talcum powder samples reported here.

The EPA R93 protocol also provides RI and BIR data for both fibrous talc and Flat Cellulose Ribbons that can be found in their Table 2.5. For the RI's of fibrous talc example, EPA reports refractive index 1.600-1.540 with a measured BIR of 0.06, and for cellulose ribbons, the reported EPA RI's are 1.580-1.530 with a measured BIR of 0.05 as shown in Table 9.

Table 9 **EPA-R93: Optical Properties of Selected Fibers**

Fibrous Talc & Cellulose Ribbons

Fiber Type	RI Parallel/Perpendicular	BIR Calculations
Fibrous Talc	1.600-1.540	0.060 "High"
Cellulose	1.580-1.530	0.050 high end of Moderate

In summary, this data demonstrates that the reported chrysotile bundles in the J&J talcum powder container samples analyzed by MAS have both the appropriate range of refractive indexes and BIR demonstrating that chrysotile asbestos was correctly identified in each container samples, and it also demonstrates that fibrous talc particles or talc plates on edge were not misidentified as chrysotile.

CSM PLM Validation Procedure for CSM Sample Preparation Method

J&J MDL Talcum Powder Sample Totals

The February 1, 2019 MDL Supplement Report for the historical J&J talcum powder products (JBP & STS) analysis demonstrated that both the Italian and the Vermont mines, that J&J sourced their talcum powder from, contained significant amounts of amphibole asbestos (tremolite & anthophyllite/cummingtonite). Additionally, the 15 MDL historical Imerys talc ore samples sourced from their Vermont mine, were found to contained tremolite asbestos. The Imerys historical retains were samples of mostly West Windsor Grade 66 which was the product that J&J used for JBP and STS form the late 1960s to 2003.

Between the MDL historical and non-historical J&J talcum powder products, along with the retain samples, MAS has analyzed a total of 118 J&J talcum powder from the Italian, Vermont and Chinese talc mine sources. The following is a breakdown between the three talc mines for the number of talc samples from each mine, that MAS has analyzed along with the number of positive samples for each group.

1960 to 1968: Italian Historical J&J Containers: of the **14 analyzed, 7 were positive** (50%) asbestos

1968 to 2003: Vermont Historical J&J Containers: of the **36 samples analyzed, 29** were positive (81%) for asbestos

1968 to 2003: Vermont Historical Imerys Retains: of the **15 samples analyzed, 8 were positive** (53%) for asbestos

1968 to 2003: Vermont Non-historical J&J Containers: of the 3 samples analyzed, 3 were positive (100%) for asbestos

2003 to 2021: Chinese Non-historical J&J Containers: of the 43 samples analyzed, 40 were positive (93%) for asbestos

2003 to 2021: Chinese Historical J&J/Imerys Retains: of the 11 samples analyzed, 11 were positive (100%) for asbestos

All total, for the three talc mine sources that suppled J&J talcum powder for their two body powder products sold in the United States, MAS has analyzed <u>96 containers of J&J talcum</u> <u>powder products</u> that had detectable concentrations of asbestos in 82% of the containers. Additionally, the <u>26 historical talc oar samples that MAS has analyzed</u>, that was sourced from the Vermont and Chinese talc mines, found <u>73% positive for asbestos</u>. ¹³

¹³ MAS Chart of J&J Testing (Current as of September 16, 2021)

Table 1

JBP Talcum Powder Sample Container Descriptions

,		Pagell	D: 1
CSM Chrys %	N/A	0.01-0.10%	0.002-0.01%
PLM Amphibole Asbestos %	N/A	NAD	NAD
ATEM Amphibole Asbestos	247,000 s/g anthophyllite	NAD	NAD
Source of Sample	Carolyn Weirick	Linda Zimmerman	Marie Colley
Sample size (oz)	9 02.	15 oz.	9 oz.
Date of Manufacture	Circa 1980	1994	1996
Sender	SGPB	SGP	SGPB
MAS Sample No.	M66514-001	M70484-001	M71046-001
	1	2	е

These three additional Vermont sourced JBP samples were all found to be positive for either amphibole asbestos or chrysotile.

J&J Chinese Talc Source Container Analysis

Tables 2 thru 6provides the J&J sample information and analytical results for the 40 JBP containers were talcum powder was sourced from China. Document 32999-23 PageID: 193711

N/A		
	N/A	
7,160 s/g	Tremolite	
	JoAnne Anderson	
	2004	
	SGPB	
	M68379-002	
8		

J&J Talcum Powder Sample Container Descriptions and Analysis Results Table 3

Samples 9 thru 16

_					1	1
	CSM Chrys %	N/A	N/A	N/A	0.0002-0.0008% 428,000 bundles/g	0.0002-0.0006% 489,000 bundles/g
	PLM Amphibole Asbestos %	N/A	N/A	N/A	N/A	N/A
	ATEM Amphibole Asbestos	NAD	17,200 s/g	NAD	NAD	NAD
anni de la companya d	Source of Sample	Krystal Kim	Krystal Kim	Nancy Cabibi	off the shelf Imperial Westwood	off the shelf Imperial Westwood
	Date of Manufacture	2017	2017	2017	2017	2017
	Sender	Lanier JBP	Lanier JBP	SGPB JBP	#2 Lanier JBP	#2 Lanier JBP
	MAS Sample No.	M66352-002	M66352-002	M68483-001	M67420-001	M67420-001
		6	12	12	12	13

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22			2018	off the shelf	N/A	NAD	0.0015-0.0017
	M71166-001	MAS JBP		CVS			
						24.4	
25		MAS JBP	2020	off the shelf	A/N	INAD	0.001-0.00%
	M71156-001			}			,
				1981e			
			((((((((((((((((((((310000 - 1037	V/IV	NAD	
25			6 707	OII (Ne SNeii	<u> </u>		0.001-0.002%
	M71166-001	MAS JBP		Walgreens			
							TANAL TO THE PARTY OF THE PARTY

Table 5 J&J Talcum Powder Sample Container Description & Analysis

Samples 25 thru 32

CSM Chrys %	%CDO 0-100 O		0.001-0.002%		0.001-0.002	
PLM Amphibole Asbestos %	NAD		N/A		N/A	
ATEM Amphibole Asbestos	N/A		N/A		N/A	
Source of Sample	off the shelf	Target	off the shelf	Holly Johnson-Walmart	off the shelf	
Date of Manufacture	2020		2020		2019	The state of the s
Sender	m, viii a a a a a a a a a a a a a a a a a	HFM JBP		Weitz JBP	Weitz JBP	
MAS Sample No.		M71180-001	M71211-001		M71211-002	
	25		26		27	

J&J Talcum Powder Sample Container Description & Analysis Table 6

Samples 33 thru 42

(I						
CSM Chrys %	0.001-0.002%	0.001-0.002%	0.001-0.002	0.001-0.002% 273,000 bundles/g	0.0009-0.001% 254,000 bundles/g	0.0007-0.001% 168,142 bundles/g
PLM Amphibole Asbestos %	N/A	N/A	N/A	N/A	N/A	N/A
ATEM Amphibole Asbestos	N/A	N/A	N/A	N/A	N/A	N/A
Source of Sample	off the shelf Holly Johnson Walmart	off the shelf Holly Johnson-Walmart	off the shelf Holly Johnson-Walmart	off the shelf Lucky	off the shelf Lucky	off the shelf Ralphs
Date of Manufacture	2019	2019	2019	2016	201\$	2018
Sender	Weitz JBP	Weitz JBP	Weitz JBP	Kazan JBP	Kazan JBP	MAS JBP
MAS Sample No.	M71180-008	M71211-009	M71211-10	M71241-001	M71241-001	M71241-001
	34	34	35	• > C	e m	38

Table 7

J&J and Imerys Guangxi Chinese Retains

Analysis for Asbestos

Samples 1 thru 11

CSM Chrys %	0.001-0.002%	0.001-0.002%	0.001%	0.001%	0.001%	0.0008-0.001%
PLM Amphibole Asbestos %	NAD	NAD	NAD	NAD	NAD	NAD
ATEM Amphibole Asbestos	NAD	NAD	NAD	NAD	NAD	NAD
BV/RJL Sample ID	BV #A5152004-006A	RJLG No. 3136120	RJLG No. 3138491	RJLG No. 313455	RJLG No. 3140762	RJLG No. 3141790
Imerys Ore Lot	N/A	N/A	MVN C01315C2	MVN S0246C2	MVN S0246C2	MVN S0246C2
Sender	Imerys Mine Seagrave	Imerys Mine Sanchez	J&J Retain	J&J Retain	J&J Retain	J&J Retain
MAS Sample No.	M71109-001	M71110-001	M71111-001	M71111-002	M71111-003	M71111-004
	~ 1	2	æ	4	5	9